INTERVIEW SUMMARY

The Applicants thank the Examiner for his time on March 31, 2009, to discuss this case. During the interview, Applicants were represented by Janet Pioli of Brinks Hofer Gilson & Lione, and Richard Godlewski of the Cook Group. The Applicants' attorneys discussed the rejections in view of the cited references, in particular Rodriguez, Radisch, Stevens, Chaisson, Ferrera, and Clayman. Applicants' representatives showed Examiner Towa a guide wire of one embodiment of the invention to help illustrate the features not taught or disclosed in the prior art, and in particular the various zones of differing stiffness or flexibility and their relationships to one another. Applicants pointed out to Examiner Towa that the primary reference relied upon (Rodriguez) does not disclose the various zones or their particular relation to one another. Applicants' representatives further pointed out to Examiner Towa that the Chaisson reference, relied on by Examiner Towa to show a J-shaped guidewire tip, does not disclose a J-shaped guidewire tip, but only a shaped catheter and that the tip of the guidewire of Chaisson is not in fact curved.

Applicants further pointed out to Examiner Towa the differences between Applicants' novel guidewire and the Stevens reference, namely that Stevens was directed to the treatment of the cardiac anatomy and discloses a device that actually penetrates the cardiac valve to reach the cardiac anatomy and that Applicants' invention, to the contrary, is addressed to treatment of the vasculature (the thoracic artery) and specifically seeks to avoid penetrating the valve

Examiner agreed to consider amendments or new claims specifically pointing out Applicants' inventive guidewire. No other agreement was reached.

REMARKS

In the Final Office Action dated February 3, 2009, claims 1, 3, 4, 7-9, 11, 12, 14, 28, and 35-47 were pending, all of which were rejected. The Applicants submitted an After-Final amendment on April 3, 20009 that was not entered. In response to the Advisory Action mailed April 7, 2009, the Applicants now submit a Request for Continued Examination along with this Amendment.

Claims 1, 3-4, 8-9, 12, 14, 36-37, 40-44 and 46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,421,349 to Rodriguez et al.

("Rodriguez") in view of U.S. Patent No. 5,295,493 to Radisch, Jr. ("Radisch"), further in view of U.S. Patent No. 5,584,803 to Stevens et al. ("Stevens") and even further in view of U.S. Patent No. 6,086,548 to Chaisson et al. ("Chaisson"). Claims 28, 35, 38-39, 45, and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rodriguez in view of Radisch, further in view of Stevens, even further in view of Chaisson, and even further in view of U.S. Patent No. 6,165,140 to Ferrera ("Ferrera"). Claims 7 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rodriguez in view of Radisch, further in view of Stevens, even further in view of Chaisson, and even further in view of U.S. Patent No. 6,716,183 to Clayman et al. ("Clayman").

Independent claims 1 and 41 have now been cancelled and replaced with independent claims 48 and 49. Dependent claims 3, 4, 7-9, 11, 12, 28, 35, 42, and 44-47 have been amended. The amendments to these claims and the addition of new claims 48 and 49 have been made for clarity purposes only and not for reasons related to patentability. Support for the amendments and the addition of new claims can be found, at a minimum, at paragraphs 55, 56, 68, and 75 and Figures 1, 3, 4, and 7. Claims 14, 36-40, and 43 have also been cancelled.

I. None of the References Teach or Disclose the Claimed Zones of Stiffness

The Office Action states that the teachings of Rodriguez include "a distal zone being comprised of three zones: a semi stiff zone adjacent to the central zone; a transition zone having high flexibility of from semi-stiff to extending to flexible; and a tip zone having high flexibility . . . ." Rodriguez's disclosure, however, regarding the flexibility of the distal end is limited to the following: "Guidewire 10 defines a distal tip 14, having a resilient, flexible tip which comprises a tapered down, thin portion 16 of the guidewire surrounded by a coil spring." (Col. 2, lines 66-68). Accordingly, Rodriguez does not teach or disclose the three zones within the distal zone or the respective stiffness of each of five zones as required by independent claims 48 and 49 set forth above.

Rodriguez further states that "the proximal tip 22 is more flexible than the central portion 11 of the guidewire 10, it is typically stiffer than the distal tip 14 because it is shorter." (Col. 3, lines 62-64). Rodriguez, therefore, does not have a portion of the distal tip 14 having a flexibility that is equal to or greater than the proximal tip 22. However, claim 48 requires the "semi-stiff zone [of the distal zone to have] a proximal portion of high stiffness adjacent to the distal portion of the central zone" and claim 49 requires a third zone to have "a semi-stiff distal portion adjacent to the proximal portion of the second zone transitioning to a proximal portion of high stiffness" that is adjacent to the fourth, or central, zone. Accordingly, both claims require a portion of the distal zone of have a higher stiffness than the proximal portion, a feature which is not found in Rodriguez.

Furthermore, Rodriguez, on its face, also does not disclose "a proximal zone . . . having a length of 5 cm to 20 cm" as required by claim 48, or "a fifth zone . . . having a length of 5 cm to 20 cm" as required by claim 49. Instead Rodriguez discloses a "[r]educed diameter portion 28 of the guidewire may be about 1 inch [2.54 cm] in length." (Col. 3, lines 27-29). The Applicants submit that it would not have been obvious to one of ordinary skill in the art at the time of the invention extend the reduced diameter portion of Rodriguez to almost double the length of what is disclosed. In fact, Rodriguez teaches away from extending the length of the reduced diameter portion as it states the shortened length makes it "possible to exert a push on the guidewire from proximal end 20 without immediate collapse of the tip 22. . . . Thus the relatively increased stiffness of the proximal tip 22 over the distal tip 14 can be advantageous . . . ." (Col. 3, line 62 – Col. 4, line 4). To extend the length of the proximal portion to over double its disclosed length would defeat any of the benefits as stated by Rodriguez. Accordingly, it would not have been obvious to one skilled in the art at the time of Applicants' invention to extend the length of the proximal end 20 by twice the disclosed length in the specification. MPEP § 2144.05.

Accordingly, it is insufficient for the Office Action to rely on the teachings, or lack thereof, found in Rodriguez, to find that each of these limitations in claims 48 and 49 are disclosed therein. The addition of Radisch, further in view of Stevens, and even further in view of Chaisson does not cure this deficiency. For this reason alone, the Applicants' submit that claims 48 and 49 are in allowable form. Similarly, dependent claims 3, 4, 7-9, 11, 12, 28, 35, 42, and 44-47 which depend from one of these independent claims are also in allowable condition for at least those same reasons.

II. There Is No Teaching Or Disclosure Of A "Pre-Formed Curve" Or A "Pre-Formed Tip Curve" Required By Claims 48 And 49.

The Office Action has failed to cite a single reference, or a combination of references, which teaches or discloses each of the elements found in independent claims 48 and 49. None of the six references cited by the Office Action teach or disclose a distal zone with a pre-formed curve or a distal pre-formed tip curve that can bump into the aortic valve without penetrating or causing damage to the valve, as required by independent claims 48 and 49. In the Final Office Action, the Examiner relied on the teachings of Stevens for the proposition that a pre-formed curve was known prior to the Applicants' invention and Chaisson for the proposition that a distal pre-formed tip curve was known prior to the Applicants' invention. As will be explained below, the Applicants respectfully disagree with the Examiner's interpretation of Stevens and Chaisson and respectfully request withdrawal of the rejection of claims 48 and 49.

For example, and as explained during the Examiner Interview, Stevens is directed towards a system for accessing a patient's cardiac anatomy and is specifically configured to penetrate, and pass through, the aortic valve. The shaft disclosed in Stevens has "a distal end, a proximal end, and a first inner lumen therebetween with an opening at the distal end in communication with the first inner lumen." (Col. 8, lines 32-34).

The Examiner points to Col. 8, lines 52-67 for support for the further proposition that Stevens discloses "a distal pre-formed U shaped curve for insertion

into a thoracic arch region of an aorta . . . ." However, the Examiner does not acknowledge that the curve of the shaft in Stevens is "imparted to the distal portion of the shaft by means of a shaping or deflecting element positioned over or within the shaft . . . ." (Col. 8, lines 56-57). Accordingly the curve in Stevens is not pre-formed but instead has a shape that is manipulated by the shaping or deflecting element. Moreover, Stevens does not teach or disclose a guidewire having "a distal pre-formed curve with a radius of curvature of from 5 cm to 15 cm" as required by claim 48 or "wherein the first, the second, and the third zones have a pre-formed curved shape" as required by claim 49, but instead is a shaft having an inner lumen disposed therein.

Furthermore, as stated in the "Summary of the Invention" section, Stevens is directed towards "effective ascending aortic occlusion, cardioplegia, venting, right heart deflation and topical cooling in association with extracorporeal cardiopulmonary by-pass . . . ." (Col. 5, lines 14-21). As shown in the annotated below figure, many of these procedures requires the penetration of a shaft through the aortic valve.

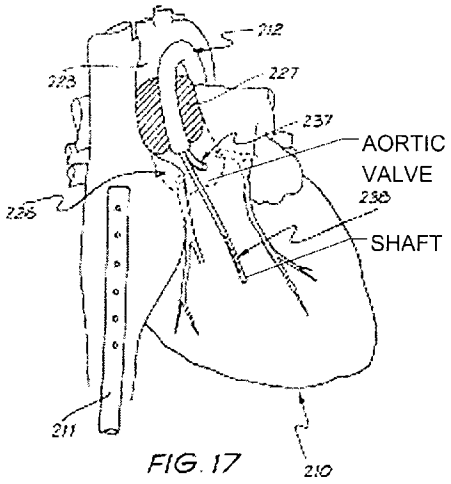


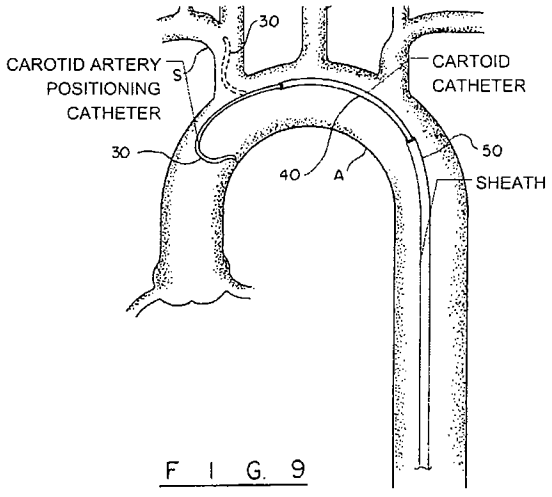
FIG. 17

Accordingly, Applicants submit that Stevens teaches away from the use of a distal tip that can bump into the aortic valve without causing damage. Moreover, it would be improper to combine Stevens with any other references which does not penetrate or pass through the aortic valve. MPEP § 2143.01.

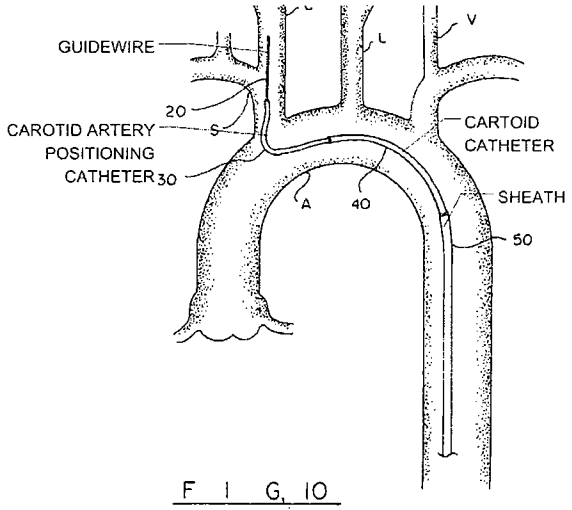
Rodriguez, Radisch, Chaisson, Ferrera, and Clayman do not cure the deficiencies found with respect to Stevens. Accordingly, the Applicants respectfully submit that independent claims 48 and 49 are in allowable form. Similarly, dependent claims 3, 4, 7-9, 11, 12, 28, 35, 42, and 44-47 which depend from one of these independent claims are also in allowable condition.

Next, the Examiner relies on the teachings Chaisson to assert that "it is known to provide endovascular devices for insertion into a thoracic arch region of an aorta with a J-shaped distal tip having a radius of curvature of about 20 mm." (Final Office Action, p. 5). The Examiner cites to figures 5 and 8 and column 4, lines 35-37 of Chaisson for support of this assertion. The Applicants respectfully disagree with the Examiner that Chaisson teaches a guide wire with an "atraumatic and highly flexible pre-formed tip curve having a single direction of curvature with a radius of curvature of from 5 to 20 mm" as required by claim 48 or a "distal pre-formed tip curve" as required by claim 49.

Instead, the disclosure the Examiner points to in Chaisson to disclose the J-shaped distal tip is that of a catheter and not a guidewire. The specification states that the "distal end 31 of the positioning catheter 30 is first advanced to the patient's aortic arch A (*see* FIGS. 5 and 9) . . . and [a]s shown in FIG. 5, the free distal end 31 [of the catheter 30] is connected to main portion 32 [of the catheter 30] with a U-shaped portion . . . ." (Col. 4, lines 29-38). Similarly, as shown in annotated FIG. 9 below, the catheter 30 forms the curved portion, not the guide wire 20.



F I G. 9



F I G. 10

The guidewire is disposed through the carotid positioning catheter and does not have a pre-formed curve as required in claims 48 and 49, as better illustrated in annotated FIG. 10 above.

Accordingly, the addition of Rodriguez, Radisch, Stevens, Ferrera, and Clayman do not cure the deficiencies found with respect to Chaisson. The Applicants respectfully disagree with the Examiner's position and respectfully request withdrawal of the rejections of claim 48 and 49. Similarly, dependent claims 3, 4, 7-9, 11, 12, 28, 35, 42 and 44-47 which depend from one of these independent claims are also in allowable condition for at least those same reasons.

III. Conclusion

In light of the above, Applicants submit that claims 3, 4, 7-9, 11, 12, 28, 35, 43, and 44-49 are in condition for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,

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